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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,149	06/22/2001	Peter W.J. Hinchliffe	BSMT117345	8108
7590	11/18/2003			EXAMINER
Neil D Gershon Rex Medical 2023 Summer St Suite 2 Stamford, CT 06905			RODRIGUEZ, CRIS LOIREN	
			ART UNIT	PAPER NUMBER
			3763	
			DATE MAILED: 11/18/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

NY

Office Action Summary	Application No.	Applicant(s)
	09/888,149	HINCHLIFFE, PETER W.J.
Examiner	Art Unit	
Cris L. Rodriguez	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 12 September 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4, 6-8, 10-12, 17, 20, 24 and 25 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4, 6-8, 10-12, 17, 20, 24 and 25 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 12 September 2003 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>5,19</u> .	6) <input type="checkbox"/> Other: _____

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on July 2, 2002 has been considered by the examiner.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: "22'" and "24'". A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The disclosure is objected to because of the following informalities: in the Brief Description of the Drawings for Figure 4, a word is missing after "another". Appropriate correction is required.
4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: "guide wire" as set forth in the claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1-4, 6-8, 10-12, 17, 20, 24, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shulze (US 6,056,721) in view of Barry et al (US 6,183,487).

Shulze discloses an angioplasty catheter (figs. 2-8) with at least three axially non-communicating passages, a guidewire lumen 28d, a guidewire 22, a first balloon 150 (fig. 8) and a second balloon 146. The second balloon can be made of a low compliance angioplasty balloon. Shulze also recognizes that in addition to the physical enlargement of flow passageways **by mechanical displacement of deposits**, modern techniques may include the use of therapeutics medicines. However, Shulze fails to disclose a rotatable guidewire for performing mechanical thrombectomy, and moot to the second balloon being made of PET (a low compliance material).

Barry teaches a guidewire 225 (figs. 16-17) extending coaxially through the burr. The wire may be keyed or coupled to the burr such that the wire and burr spin simultaneously for material removal in a stenosed vessel, or independently from the burr. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute Shulze's guidewire with the one shown in Barry. Doing so would have removed material from a stenosed vessel by a mechanical alternative such as a rotatable wire. Furthermore, the selection of a well known material has been rendered as an obvious design choice, since the selection of a known material based on its suitability for its intended use supported a *prima facie* obviousness determination in *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S.

327, 65 USPQ 297 (1945). In this case, PET as a low compliance material for the angioplasty balloon.

Response to Arguments

7. Applicant's arguments filed September 12, 2003 have been fully considered but they are not persuasive.
8. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).
9. In response to applicant's argument that there is no teaching or suggestion to modify the Schulze's device to provide a mechanical obstruction treatment device as Barry, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Schulze and Barry devices are for removing deposits within the vessel. But the difference between both is that Schulze is a non-mechanical way, and Barry is. These are alternatives ways to remove unwanted deposits with the vessel.

10. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the suggestion to combine the references is that Schulze and Barry devices are for removing deposits within the vessel. However, Schulze is by a drug delivery method, and Barry is by a mechanical method. Barry's guidewire goes beyond its conventional intended purpose and includes an abrasive tip to remove unwanted deposited material in the vessel, since the guidewire rotates independently from the burr (Fig. 17). Therefore, it would have been obvious to substitute Schulze's guidewire for Barry's in order to provide a mechanical way to remove a deposit.

11. In response to applicant's arguments to Schulze's catheter, its intended purpose is no different as applicant that is to perform angioplasty and to deliver a guidewire. Schulze also treat the deposits in a non-mechanical way.

12. In response to applicant's argument that Schulze is for angioplasty and drug delivery, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

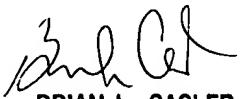
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

November 12, 2003


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700


Cris L. Rodriguez
Examiner
Art Unit 3763